



UNITED STATES DEPARTMENT OF COMMERCE  
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SERIAL NUMBER FILING DATE  
07/445,632 11/27/89 NANKAI

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TJD27878PCT

BELL, B

STEVENS, DAVIS, MILLER AND MOSHER  
P.O. BOX 1427  
ALEXANDRIA, VA 22313

112

08/08/91

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ \_\_\_\_\_

Part II SUMMARY OF ACTION

1. ☒ Claims 1-18 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 1-18 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-18 are rejected under 35 U.S.C. § 103 as being unpatentable over Nankai et al.

Nankai et al teaches:

- (1) biosensor with an insulating base plate and reaction layer and an electrode system which is formed mainly of carbon in which an oxidoreductase, an electron acceptor and liquid sample are reacted with one another.
- (2) electrode surface is coated with a protein
- (3) conductive carbon base with resin binder printed by screen printing on insulative base followed by heating for drying electrode system
- (4) perforated body having enzyme and electron acceptor is placed in hole of frame.

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(5) resin cover having an opening smaller than ~~outer~~ diameter of perforated body is adhered.

(6) glucose oxidase as an ~~oxy~~do-reductase

(7) potassium ferricyanide as the electron acceptor.

(8) filtration layer made of polycarbonate film having a pore size of 1um mounted on a layer and fixed with a holding frame.

Claims 1-5, 7-10, 14 are rejected under 35 U.S.C. § 103 as being unpatentable over Nankai et al in view of Otagawa et al.

Otagawa et al teaches:

(1) microsensor structure with a plurality of electrodes with gaps being bridged by a solid polymer electrolyte.

(2) use of a polymer that is hydrophilic whereby signals from the sensor are made humidity independent

(3) membranes made of carboxycellulose, gelatin, methylcellulose, vinyl alcohol, and polyvinyl pyrrolidone.

Claims 13, 15-17 are rejected under 35 U.S.C. § 103 as being unpatentable over Nankai et al and Otagawa et al in view of Higgins et al.

Higgins et al teaches:

(1) a mediator component (electron acceptor) which transfers electrons from the enzyme to the electrode.

(2) a silver electrode coated with glucose oxidase and a mediator or a carbon electrode coated with glucose oxidase and a mediator

- (3) mediator compound is a ferrocene or ferrocene derivative
- (4) electrode comprises a carbon core, layer of ferrocene, layer of glucose oxidase and a hydrophilic gel layer.

Claims 13 and 18 are rejected under 35 U.S.C. § 103 as being unpatentable over Nankai et al and Otagawa et al in view of Newman.

Newman teaches:

- (1) a laminated membrane comprising a layer of cellulose acetate, an adhesive layer of enzyme with or without other material blended and a support film layer which prevents a high molecular weight interfering material.

It appears to the examiner that from the prior art that the membrane layers may be manipulated in any order to achieve the expected results wanted. Applicant must show evidence that there is a patentable difference in result between their invention and the prior art of record.

It would be obvious to one skilled in the art to modify Nankai et al with Otagawa et al, Higgins et al and Newman because Nankai et al shows a singular electrode system and Otagawa et al shows plural electrode systems for determining concentration of a sample solution. Higgins et al and Newman show different membranes and methods of producing and layering to determine the concentrations of the sample solution.

The prior art made of record and not relied upon is

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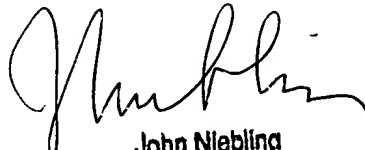
considered pertinent to applicant's disclosure.

Art recited but not relied upon by the examiner teaches a multilayer enzyme electrode membrane.

Any inquiry concerning this communication should be directed to Bruce Bell at telephone number (703) 308-2543.

*BFB.*

B.Bell:mm  
August 07, 1991

  
John Niebling  
Supervisory Patent Examiner  
Patent Examining Group 110